

REMARKS

1. The Amendments and the Support Therefor

No claims have been canceled, six new claims (76-81) have been added, and claims 51, 64, and 68 have been amended to leave claims 51, 53, 55-64, 67, 68, and 70-81 in the application. Payment for any newly-submitted claims in excess of the amount previously paid for should accompany this Response, as per 37 CFR §1.16(b)-(d), with the fee due being calculated as follows:

FEE CALCULATION

For	Already Paid	No. Extra	Rate (SMALL ENTITY)	Fee (SMALL ENTITY)
Total Claims	26 - 20 =	6	x \$25 =	\$150
Independent Claims	4 - 4 =	0	x \$105 =	\$0
Total:				\$150

No new matter has been added by the amendments or new claims, wherein new claims 76-78 find support in FIG. 3 and FIGS. 79-81 find support in FIG. 1 (compare 4, 5, 6 with 2). Further comments regarding the new claims are set out below.

2. Sections 2-3 of the Office Action: Rejection of Claims 64, 67, 68, 71 and 72 under 35 USC §102 in view of U.S. Patent 1,036,229 to Harrild

Harrild is directed to an improved dowel which provides advantages over an ordinary dowel (i.e., a simple rod) when used for attaching opposing pieces of wood. The *Harrild* dowel has a center piece 2 similar to a conventional dowel, which can be struck to drive it into a piece of wood. Side spurs 1 angle off of the center piece 2 when the dowel is driven into wood so that the spurs 1 firmly anchor the center piece 2 in the wood. To anchor one piece of wood to another, the opposing ends of the dowel must be embedded in opposing pieces of wood.

Claims 51, 64, and 68 have been amended to differentiate the inventions claimed therein from the *Harrild* device by excluding structure such as the center piece 2 of *Harrild* from the claimed invention. Further, it would not be obvious to modify *Harrild* to meet the claimed structure: no ordinary artisan would contemplate modifying *Harrild* to meet these claims because *Harrild*'s center piece 2 is the primary structure which holds the opposing pieces of wood in the desired opposing relationship – it is the dowel which fixes the wood as desired – and the side spurs 1 serve to prevent withdrawal of the dowel. Further, as noted by *Harrild* at lines 24-29, the center piece 2

is necessary to allow the spurs 1 to be successfully driven into wood without damage, and thus an ordinary artisan would not contemplate removal of the center piece 2. See MPEP 2143.01 at Section V (“The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose”).

New claims 76-78, which recite the inventions of claims 51, 64, and 68 in their in-use states, are also novel because *Harrild* is plainly not used between, nor is it contemplated for use between, a graft and an artery. Even if the wooden parts of *Harrild* are regarded as equivalent to a graft and an artery, the devices of these claims are still novel: in the recited devices, the first and second parts extend *through* the structures which they attach, and then at least partially extend *adjacent the surfaces* of these structures. In contrast, the first and second parts (the spurs 1) of *Harrild* are entirely embedded within the structures into which they extend; none of the *Harrild* spurs 1 extends entirely through its piece of wood and then adjacent its outer surface. Further, these claims are also unobvious because no ordinary artisan would provide the *Harrild* device between a graft and an artery as recited: one center piece 2 of the *Harrild* device would extend within the interior of the graft and obstruct it, and the opposing center piece 2 of the *Harrild* device would extend through the artery wall and into adjacent tissue, which would cause unnecessary trauma. (Claim 63, which is subject to an obviousness rejection as set forth below, is submitted to be novel and unobvious for these same reasons.)

In similar respects, new claims 79-81 are also novel in view of *Harrild*, wherein the center pieces 2 along the axis of the dowel retain their length both when the spurs 1 are in parallel/open and in deployed/retaining positions. These claims are also unobvious, again because no ordinary artisan would contemplate removing *Harrild*'s center piece 2 or otherwise modifying the *Harrild* device to meet these claims.

3. Sections 4-5 of the Office Action: Rejection of Claims 51, 53, 55-61, 63, 70 and 73-75 under 35 USC §103(a) in view of U.S. Patent 1,036,229 to Harrild and U.S. Patent 6,994,713 to Berg et al.

Berg et al. relates to a plug/connector whose characteristics were discussed in detail in the prior Response. *Berg et al.* notes at column 5 lines 47-57 the possibility of forming the plug/connector of shape-memory material such as nitinol such that the plug/connector can be supercooled (at which point it will be highly plastic, and can be deformed into an undeployed/open state), and then installed, such that it will deform into its original (deployed/retaining) shape once it warms up within a body.

Kindly reconsider and withdraw these rejections. As discussed above, no artisan would regard *Harrild* as being suitable for use as a fixator for grafts (or for any other biological matter): the central portions 2 of *Harrild* would protrude from the fixator at its point of attachment (e.g., into the interior of any graft and artery being fixed, and/or into the surrounding tissue), making *Harrild* unsuitable for such use. As a result, the rationale for the modification – that making *Harrild* of shape-memory material would “produce a strong device that is biocompatible and corrosion-resistant, and it would improve the retention between parts joined together by biased elongated members” – does not provide a valid justification for why one of ordinary skill would make the modification. An ordinary artisan would not regard *Harrild* as suitable for biological use – it is a wood fastener – and thus there is no real reason why one would form *Harrild* of (expensive) shape memory material. Conversely, if *Harrild* was used for woodworking applications rather than biological applications, the modification makes no sense: since *Harrild*’s spurs 1 are intended to be spread at the time when *Harrild* is installed into wood (and not *after* installation, as in *Berg*), there is no reason to form *Harrild* to be formed of shape memory material. Further, even if *Harrild* was formed of shape memory material, it would yield no benefit because the wood into which the spurs are embedded would not permit the *Harrild* spurs to bend into a new shape, regardless of any temperature change experienced by the spurs. It is apparent that this rejection was made in hindsight: if the claimed invention is placed out of mind, and *Harrild* and *Berg et al.* are viewed from the standpoint of one of ordinary skill in the art, what would *truly* lead one to adapt *Harrild* for

biological use, and form it of shape memory materials for the sake of achieving some advantage in biological applications? Conversely, why would one *truly* form *Harrild*'s fixator of shape memory materials for use in woodworking applications?

As for the rationale that "it would be obvious to apply a shape memory alloy in the device of *Harrild* since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice," this is conclusory, and does not remedy the deficiencies noted above: *Harrild* is not suitable for an intended biological use, nor are shape memory materials suitable for woodworking use of *Harrild*. This rationale, which is apparently extracted from MPEP 2144.07, does not rationally support a determination of obviousness in this case. See, e.g., *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007): "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

4. Sections 7-8 of the Office Action: Allowance of Claim 62

The indication that claim 62 is allowable is noted and appreciated.

5. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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